IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Laurent Schaller et al.	Examiner: Woo, Julian W.
Serial No.: 10/653,027	Group Art Unit: 3773
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Title: TISSUE CONNECTOR APPARATUS AND METHODS

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In response to the Final Office Action dated February 25, 2009, Applicants request a pre-appeal brief review because of clear errors in the Examiner's rejections. This paper is being filed together with a Notice of Appeal and a one month extension of time thereby moving the deadline for response to June 25, 2009.

Summary of the Rejections

Claims 1, 3, 5, 9, and 10 were rejected under 35 U.S.C. §102(b) as being anticipated by Seitzinger U.S. Patent No. 5,362,294 ("Seitzinger")[1]; Claims 1, 28, 29, 31 and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by Pyka et al U.S. 5,002,563 ("Pyka"); Claims 33-35 were rejected under 35 U.S.C. §102(e) as being anticipated by Bolduc et. al. U.S. Patent No. 6,254,615 ("Bolduc"); Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Seitzinger in view of Kaufman et. al. U.S. Patent No. 3,125,095 ("Kaufman"); Claims 11 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Seitzinger in view of Totakura et. al. U.S. Patent No. 5,383,904 ("Totakura").

The Cited References Distinguished

Seitzinger

In rejecting independent claims 1, 3, 5, 9. and 10 as being anticipated by Seitzinger, the Examiner advanced that Seitzinger discloses at least in the figures and in col. 2 lines 28-65, a tissue connector assembly where the assembly includes first and second tissue piercing members (16,18) and a surgical fastener (10) adapted to assume a loop configuration.

Independent claim 1 is patentably distinguishable from, and is allowable over, Seitzinger for at least the following reasons. Claim 1 describes in part a tissue connector

[1] On March 16, 2009 Examiner Woo placed a call to Applicants confirming that the intended patent number was U.S. Patent No. 5,362,294 to Seitzinger (U.S. Patent No. 5,374,268 to Sander was listed while referring to Seitzinger).

assembly comprising a surgical fastener, which is adapted to assume a loop configuration, a first tissue piercing member coupled to a first end portion of the surgical fastener, and a second tissue piercing member coupled to a second end portion of the surgical fastener. Applicants submit that Seitzinger does not disclose a tissue connector assembly comprising a surgical fastener. Contrary to the Examiner's assertion, member 10 of Seitzinger is described as a sling comprising an elongated web having lead sutures connected at opposite ends (col. 2 lines 28-29). The sling is described as useful for retracting a body organ during a laparoscopic surgical procedure so that the organ does not interfere with the surgical procedure. Seitzinger gives the example of a gynecological laparoscopy wherein it is often necessary to manipulate or position the uterus. (col. 1 lines 30-40). In no instance does Seitzinger disclose the use of a sling to connect or fasten anything. Seitzinger is devoid of any mention of the use of the body organ sling 10 as a surgical *fastener*. Applicants respectfully submit it is clear error to equate the organ retracting sling device of Seitzinger with a tissue connector assembly let alone a surgical fastener.

Pyka et al.

In rejecting Claims 1, 28, 29, 31 and 32 under Pyka the Examiner advanced that Pyka discloses a tissue connector assembly (1) including a surgical fastener (18 or 12) adapted to assume a loop configuration, a first tissue piercing member (14), a second tissue piercing member (32 with a sharpened distal end) and a flexible member comprising a suture (16) where the surgical fastener has first and second end portions, the first tissue piercing member being coupled to the first end portion and the second tissue piercing member being coupled to the second end portion (via 18).

Independent Claim 1 is patentably distinguishable from, and is allowable over, Pyka for at least the following reasons. The Examiner advanced that sleeve 32 of Pyka is a second tissue piercing member as required by claim 1 and that sleeve 32 is coupled to a second end portion via element 18 of surgical fastener 18 or 12. However, sleeve 32 is not coupled to a *second end portion* of either element 12 or 18. Rather, as disclosed in Pyka at col 7 lines 2-12, "The stiff sleeve 32 prevents the shape memory change from occurring prematurely…when the suture 10 is to be used…the sleeve can thus be removed just before the suture 10 is placed into the tissue 24. Alternatively, the sleeve 32 can be used to directly drive the needle 14 through the tissues 24…The sleeve can also have a sharpened distal end and can be used to push the member 18 through the tissue 24. Generally, the needle 14 should be held by the sleeve 32 in such an instance so that relative rotation is prevented." The Examiner's assertion that a first tissue

piercing member is connected to a first end portion (via 16) appears to imply that element 16 is a first end portion. According to the disclosure of Pyka, elements 16 and 26 are first and second end portions respectively of member 18. As clearly seen in Fig. 3, sleeve 32 is not coupled to second end portion 26, nor does the Examiner assert that sleeve 32 is so coupled. Thus, the Examiner's assertion that sleeve 32 is coupled to a second end portion (not defined by the Examiner) "via 18" does not make sense and Pyka clearly does not set forth every element as recited in Applicants' claim 1.

Bolduc et al

In rejecting independent claims 33-35 as being anticipated by Bolduc, it was advanced that Bolduc discloses in figures 12F and 12G and in column 16, line 62 to column 17, line 14 a tissue connector assembly including a surgical fastener (222) adapted to assume a loop configuration and having first and second end portions, a first discrete tissue piercing member (point of 220a) coupled to the first end portion and a second tissue or discrete tissue piercing member (point of 220b) coupled to the second end portion.

Regarding independent claims 33-35, Bolduc does not disclose or suggest an assembly comprising (1) a fastener and (2) two tissue piercing members, let alone one tissue piercing member "coupled" to one end portion of the fastener or another tissue piercing member that is "coupled" to another end portion of the fastener.

Independent Claims 33 and 34 also emphasize the separateness of the tissue piercing members with reference to them as being discrete. Bolduc clearly does not disclose or suggest discrete tissue piercing members. The tissue piercing members in Bolduc are part of a single fastener and are not individually separate and distinct elements. The Examiner's Final Rejection provides clear guidance regarding this claim language. The Examiner sets forth that an individual part is a "separate and distinct part of a whole". According to the Examiner's own assertion then, the tissue piercing members (220a and 220b) which are integral parts of the Bolduc fastener, cannot also be separate and distinct. Thus, Bolduc does not meet the language of claims 33 and 34 which describe discrete tissue piercing members.

Independent Claim 35 describes in part a surgical fastener as comprising a surgical clip having open and closed configurations where the clip assumes a spiral configuration when in the closed configuration. As shown in FIG. 12G, clip 192f of Bolduc does not assume a spiral configuration when in a closed configuration. Applicants maintain that the end portions of the clip are not shown as getting progressively farther away from the central point of the clip as those

portions revolve around that point. Although portions of the clip cross over one another, the clip does not assume a spiral configuration as claimed.

Seitzinger in view of Kaufman

Claims 6 and 8 are allowable at least by virtue of their dependency from an allowable claim as set forth above with regard to the 102(b) rejection based upon Seitzinger. In addition, Seitzinger provides at col. 2 lines 45, "In the preferred embodiment, the web 10 is made of a biocompatible surgical sponge such as MEROCEL sponge…is a polymeric, elastomeric ling-free, uniformly swellable, hydrophilic sponge having a uniform pore geometry and pore size distribution throughout its volume..the sponge when dry, can be packed into a small tube but expands when moistened to form a soft, flexible material capable of retracting a uterus or other body organ." Seitzinger also provides, "the uterus cannot be manipulated by instruments that would tend to penetrate or otherwise damage it." col. 1 lines 39-41. There exists no motivation either in the art or the references to modify the Seitzinger sling made of a sponge material such that the sling be made of flexible stainless steel sutures. Nor does there exist any plausible explanation as to how this modification would or could be carried out while maintaining the attributes of the Seitzinger device such that the device may be packed into a small tube and expanded to form a soft flexible device capable of retracting a body organ without damage. From the foregoing it is clear that Seitzinger teaches away from forming the sling of a multi-filament stainless steel wire as taught by Kaufman.

Seitzinger in view of Totakura

Claims 11 and 18 are allowable at least by virtue of their dependency from an allowable claim as set forth above with regard to the 102(b) rejection based upon Seitzinger. In addition, contrary to the Examiner's position, the stiffening agent 22 of Totakura is not a coupling. Totakura discloses a stiffening agent 22 disposed on at least a portion of the suture *adjacent the pledget, most preferably* about 10 to about 20% the length of the suture portions. Col. 2 lines 5-25. It is clear from the disclosure of Totakura that the stiffening agent 22 does not couple the needle to the suture. The figure shows needles 16a, 16b attached to sutures 12a, 12b while no stiffening agent is present at the needle/suture junction. In addition, the preference to have the stiffening agent well below the junction is made clear in the specification as set forth above. Finally, the stiffening agent is described as a biocompatible material capable of stiffening the suture to eliminate tangling or twisting of suture positions and is preferably liquid or liquid soluble. Col. 22-27. Nowhere does Totakura describe a stiffening agent for use as a coupling and

indeed, element 22 does not couple anything. Furthermore, Seitzinger discloses that the material used to manufacture the sling 10, the so-called "fastener", can be folded with the needles and sutures inside the material for ready insertion through a 10 mm port. Seitzinger's Fig. 2 shows a cannula 20 with a sling 10 wound to reduce its size within the cannula, the needles and sutures being retained inside. If, as the Examiner suggests, the entire length of the sutures of Seitzinger were to be coated with the stiffening agent 22 of Totakura, the sutures would likely not be amenable to being folded for insertion into a cannula as described above.

The Examiner's failure to address these issues constitutes clear error. The additional dependent claims not discussed specifically herein are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims.

Applicant further notes Applicant filed a pre-appeal request for review in related, co-pending, co-owned U.S. Patent Application No. 10/208,405 on December 29, 2008 in response to an Office Action that included rejections based on Bolduc et al. Applicant assumes the review panel has access to the prosecution for this file, but will provide a copy if required.

CONCLUSION

It is respectfully submitted that this application is now in condition for allowance, and such action is requested. If the Examiner believes a telephone interview would be useful, please call the undersigned at the phone number below. The Commissioner is hereby authorized to charge any fee determined to be due in connection with this communication, or credit any overpayment, to our Deposit Account No. 13-2546.

Respectfully submitted,

Date June 25, 2009

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